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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/266,543 03/11/99 HOLADAY

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HM12/0925

EXAMINER

HOLLERAN, A

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

09/25/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/266,543

Applicant(s)

HOLADAY ET AL.

Examiner

Anne Holleran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-13, 15-23 and 25-49 is/are pending in the application.
- 4a) Of the above claim(s) 30-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-13, 15-23 and 25-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

1. The amendment filed July 18, 2001 is acknowledged.

Claims 4, 14, and 24 were canceled.

Claims 5-13, 15-23, and 25-49 are pending.

Claims 30-49, drawn to non-elected inventions, are withdrawn from consideration.

Claims 5-13, 15-23 and 25-29 are examined on the merits.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. The amendment to the specification to correct the priority of the instant application is acknowledged. However, now this statement is not the same as the information contained in the declaration, which states that the instant application is a continuation of 09/265,213, filed March 10, 1999.

Claim Rejections Withdrawn:

4. The rejection of claims 5, 6, and 25 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention are withdrawn in view of the amendment.

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5. The rejection of claims 4, 5, 14, 24 and 25 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of the amendment.

6. The rejection of claims 4-23 under 35 U.S.C. 102(e) as being anticipated by U.S. Patent 5,919,459 (Nacy et al), is withdrawn in view of the declaration filed under 37 C.F.R., 1.132.

7. The rejection of claims 4-29 rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,919,459 (Nacy et al), is withdrawn in view of the declaration filed under 37 C.F.R., 1.132.

8. The rejection of claims 5 and 7-13, and 25-29 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15-21, 28, 29, 32, and 33 of U.S. Patent No. 5,919,459 is withdrawn in view of the amendment to claims 5 and 25.

Claim Rejections Maintained and New Grounds of Rejection:

9. Claims 5-13, 15-23 and 25-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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✓ Claims 5, 15 and 25 are indefinite because “the heparin binding domain” and “the receptor binding domain” lack antecedent basis.

/ Claim 15 remains indefinite because of the recitation of the word “corresponds”. (Note the clean copy of claim 15, which was entered, contains the word “corresponds”, whereas the marked up version contains the phrase “consists of”).

10. ✓ Claim 6 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 6 depends from claim 5. Claim 5 recites closed language, “consisting of” to define an immunogenic peptide fragment. However, claim 6 broadens the scope of claim 5 by using open language, “comprising” to define the structure of an immunogenic peptide fragment.

11. Claims 15-23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 15 remains rejected for the reasons of record. Dependent claim 16 is newly rejected because the specification fails to teach immunogenic compositions comprising a peptide that comprises SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9, but instead teaches immunogenic compositions

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that comprise a peptide that consists of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. Dependent claims 17-23 are newly rejected because they depend from claim 15, which is drawn to subject matter that is not adequately disclosed in the specification. The specification does not teach immunogenic compositions that correspond in structure to a receptor binding domain of vascular endothelial growth factor, because the specification does not provide adequate descriptive support for a genus of immunogenic peptides where the peptide has a structure other than a peptide consisting of SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID NO: 6, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9. Furthermore, the specification fails to teach fragments of the claimed immunogenic peptides that correspond in structure to a receptor binding domain of vascular endothelial growth factor.

12. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Senoo, M. et al (EP281822, European Patent Application, Takeda Chemical Industries, Ltd.; published September 14, 1988) is maintained for the reasons of record.

Claim 6 is drawn to compositions comprising a peptide that comprises SEQ ID NO: 1 or SEQ ID NO: 2. Senoo teaches immunogenic peptides that comprise the amino acid sequence of SEQ ID NO: 1 or SEQ ID NO: 2.

13. Claims 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by Ungheri et al (U.S. Patent 5,288,704; issued 02/22/1994). Because the instant application is a continuation-in-part of the parent application, which does not appear to have contemplated immunogenic

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fragments that consist of the heparin binding domain of fibroblast growth factor, and fails to disclose SEQ ID NO: 1 or SEQ ID NO: 2, the effective filing date of the instant application is considered to be the filing date with which to compare the claims with the prior art.

Claims 5 and 6 are drawn to immunogenic compositions comprising immunogenic fragments of fibroblast growth factor. For claim 5, the immunogenic fragment consists of a heparin binding domain of fibroblast growth factor. For claim 6, the immunogenic fragment comprises SEQ ID NO: 1 or SEQ ID NO: 2. The recitation of "immunogenic" is considered to be a recitation of intended use and need not be taught by a prior art reference that teaches the claimed peptides.

Ungheri teaches pharmaceutical compositions comprising a peptide consisting of SEQ ID NO: 9 which is a peptide that comprises SEQ ID NO: 2 (see enclosed sequence alignment, abstract, and claim 1). Because Ungheri's SEQ ID NO: 9 appears to be the sequence of a heparin binding domain, and because SEQ ID NO: 9 of Ungheri comprises SEQ ID NO: 2, Ungheri discloses compositions that are the same as that claimed.

14. Claims 6, and 15-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15-21, 28, 29, 32, and 33 of U.S. Patent No. 5,919,459. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 6 is broadly drawn to compositions comprising SEQ ID NO: 1 or SEQ ID NO: 2, which reads on the entire fibroblast growth factor, and because claims 15-23 are broadly drawn to compositions comprising receptor binding fragments of vascular endothelial growth factor, or comprising SEQ ID NO: 3, SEQ ID NO: 4, SEQ ID NO: 5, SEQ ID

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NO: 6, SEQ ID NO: 6, SEQ ID NO: 7, SEQ ID NO: 8 or SEQ ID NO: 9, which read on compositions comprising the entire vascular endothelial growth factor.

Conclusion

No claim is allowed. This rejection is not made final because of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the Office should be directed to Anne Holleran, Ph.D. whose telephone number is (703) 308-8892. Examiner Holleran can normally be reached Monday through Friday, 9:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached at (703) 308-3995.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

AH
Anne L. Holleran
Patent Examiner
September 24, 2001

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